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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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|-----------------|-------------|----------------------|---------------------|------------------|

10/549,811

09/14/2006

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Q74728

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23373 7590 04/02/2009
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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

04/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/549,811 | Applicant(s) OHYAMA ET AL. | |
| | Examiner Alana M. Harris, Ph.D. | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/19/2005; 05/14/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-10) in the reply filed on October 3, 2008 is acknowledged.

2. Claims 1-13 are pending.

Claims 11-13, drawn to non-elected inventions and are not examined on the merits.

Claims 1-10 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 9 is vague because it reads on a method for detecting prognosis of cancer which comprises detecting core-2 beta-1,6-N-acetylglucosaminyltransferase in a sample collected for a biological organism before resection of a cancer tissue. It seems the first recited independent claim, claim 1 already notes the detection of the candidate marker in a biological sample. It seems the only means in accomplishing the detection

is to remove the biological sample. Claim 9 does not seem to further limit from claim 1 and seems redundant. Applicants are requested to further clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al./U.S. Patent number 6,136,580 (issued October 24, 2000). Fukuda discloses a method of detecting mammalian polypeptide core 2, core 4 and I branching β 1,6-*N*-acetylglucosaminyltransferase (C2GnT-M) and core 2 β 1,6-*N*-acetylglucosaminyltransferase (C2GnT-L) in various human tissues and cancer cell lines using immunological procedures, see Figure 8; column 15, lines 31-42; column 20, Example IV.

7. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Machida et al. (Cancer Research 61: 2226-2231, March 1, 2001). Machida discloses a method of detecting core 2 β 1,6-*N*-acetylglucosaminyltransferase (C2GnT) mRNA in

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surgically dissected tissue specimens of lung cancer, see abstract and Tissue Specimens section on page 2226.

8. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimodaira et al. (Cancer Research 57: 5201-5206, December 1, 1997/ IDS reference submitted September 19, 2005). Shimodaira discloses a method of detecting carcinoma-associated expression of C2GnT in colorectal cancer specimens, see abstract. Biopsy specimens of carcinoma tissues were obtained during surgical operation, see page 5201, Patients section; and bridging sentence of columns on page 5202.

9. Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Ohyama et al. (Glycobiology 13(11): 864, November 2003/ IDS reference submitted May 14, 2007). Ohyama discloses an immunohistochemical detection of core 2 fA-1,6-N-Acetylglucosaminyltransferase (C2GnT) in prostate needle biopsy specimens, see Purpose and Materials...sections. Although the reference does not explicitly cite a C2GnT antibody it is art known immunohistochemical detection implements antibodies specific for a target antigen.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

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(571)272-0831. The Examiner works a flexible schedule, however she can normally be reached Monday through Saturday, 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
26 March 2009
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643